

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
SANFORD T. COLB
SANFORD T. COLB & CO.
P.O. BOX 2273
76122 REHOVOT
ISRAEL

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 61824	Date of mailing (day/month/year) FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IL07/00600	International filing date (day/month/year) 17 May 2007 (17.05.2007)
Applicant SMART MEDICAL SYSTEMS LTD	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Linda C.M. Dvorak <i>[Signature]</i> Telephone No. 703-308-2193 <i>[Signature]</i>
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Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 61824	Date of mailing (day/month/year) 19 MAY 2008
International application No. PCT/IL07/00600	International filing date (day/month/year) 17 May 2007 (17.05.2007)
Applicant SMART MEDICAL SYSTEMS LTD	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

 For more detailed instructions, see the notes on the accompanying sheet.
2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
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 - ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. **Reminders**
 Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.
 The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.
 Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.
 In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.
 See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Linda C.M. Dvorak Telephone No. 703-308-2193
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Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 61824	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below</small>	
International application No. PCT/IL07/00600	International filing date (day/month/year) 17 May 2007 (17.05.2007)	(Earliest) Priority Date (day/month/year) 18 May 2006 (18.05.2006)
Applicant SMART MEDICAL SYSTEMS LTD		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the **language**, the international search was carried out on the basis of:

☒

the international application in the language in which it was filed.

☐

a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐

This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 Rule 43.6 *bis(a)*

c. ☐

With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐

Certain claims were found **unsearchable** (See Box No. II)

3. ☐

Unity of invention is **lacking** (See Box No. III)

4. With regard to the title,

☒

the text is approved as submitted by the applicant.

☐

the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒

the text is approved as submitted by the applicant.

☐

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

☒

as suggested by the applicant.

☐

as selected by this Authority, because the applicant failed to suggest a figure.

☐

as selected by this Authority, because this figure better characterizes the invention.

b. ☐

none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL07/00600

A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61B 1/00(2006.01)

USPC: 600/116

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/101,115-116,121-125; 606/96.01-103

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6585639 B1 (Kotmel; Robert et al.) 01 July 2003 (01.07.2003) entire doc	1-6,9-25,27,29-42,44-46,48-57,59-75,77-87
Y	US 6309346 B1 (Farhadi; Ashkan) 30 Oct 2001 (30.10.2001) entire doc	7,8,26,28,43,47,58,76
A	US 4453545 A (Inoue; Hiroshi) 12 Jun 1984 (12.06.1984) entire doc	1-87
A	US 4862874 A (Kellner; Hans-Jorg) 05 Sep 1989 (05.09.1989) entire doc	1-87

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

21 April 2008 (21.04.2008)

Date of mailing of the international search report

19 MAY 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Authorized officer

Linda C.M. Dvorak
Telephone No. 703-308-2193

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To:
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 61824		Date of mailing (day/month/year) 19 MAY 2008	
International application No. PCT/IL07/00600		International filing date (day/month/year) 17 May 2007 (17.05.2007)	
International Patent Classification (IPC) or both national classification and IPC IPC: A61B 1/00(2006.01) USPC: 600/116		Priority date (day/month/year) 18 May 2006 (18.05.2006)	
Applicant SMART MEDICAL SYSTEMS LTD			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

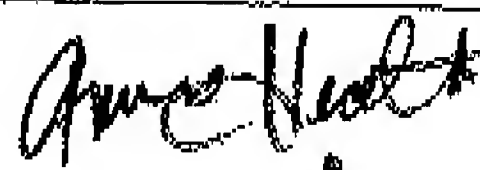

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 21 April 2008 (21.04.2008)	Authorized officer Linda C.M. Dvorak  Telephone No. 703-308-2193 
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Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL07/00600

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43b/s.1(a))
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:
- a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL07/00600

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Inventive step (IS)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Industrial applicability (IA)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL07/00600

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 7-8, 26, 28, 43, 47, 58, 76

The opinion as to Novelty was negative (No) with respect to claims 1-6, 9-25, 27, 29-42, 44-46, 48-57, 59-75, 77-87

The opinion as to Inventive Step was positive (Yes) with respect to claims NONE

The opinion as to Inventive Step was negative (NO) with respect to claims 1-87

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-87

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1-6, 9-25, 27, 29-42, 44-46, 48-57, 59-75, 77-87 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent No. 6,585,639 to Kotmel et al.

In regard to claims 1-2, 21-22, 27, 39, 59-60, 67-68, 72, 77-80 and 84-85, Kotmel et al. disclose an enhanced flexibility auxiliary endoscope assembly for use with an endoscope, the assembly comprising: at least one flexible elongate element; and a flexible sleeve 26 having a first lumen 62 for accommodating a distal portion of an endoscope 14 capable of assuming at least a first curvature and a second lumen 64 for accommodating said at least one flexible elongate element, said second lumen being configured to allow said at least one flexible elongate element to assume said at least first curvature as well as at least a second curvature about said first curvature, thereby to enhance flexibility of said auxiliary endoscope assembly (see Figs. 1, 3d and Col. 4, Lines 30-50, Col. 9, Lines 32-38).

In regard to claims 3, 44-46 and 61, Kotmel et al. disclose an enhanced flexibility auxiliary endoscope assembly for use with an endoscope wherein at least part of said second lumen has a generally saddle shaped cross section, adapted to enable said at least one flexible elongate element to be slidably displaced laterally in accordance with said first curvature (see Figs. 3d, f).

In regard to claims 4, 23 and 40, Kotmel et al. disclose an enhanced flexibility auxiliary endoscope assembly for use with an endoscope also comprising an inflatable balloon 34 mounted onto said flexible sleeve (see Fig. 1 and Col. 4, Lines 5-19).

In regard to claims 5-6, 11-13, 24-25, 31, 41-42, 50, 62-64, 69, 73 and 81, Kotmel et al. disclose an enhanced flexibility auxiliary endoscope assembly for use with an endoscope, wherein the flexible elongate element is an endoscope tool which extends through a channel and is capable of including an inflatable endoscope tool (see Col. 11, Lines 14-28). The viewing scope remains in place and a plug, or other endoscopic instrument such as an inflatable balloon is introduced through a separate access lumen (i.e. 64, 82) present in the sheath itself.

In regard to claims 9-10, 29-30, 48-49 and 86-87, Kotmel et al. disclose an enhanced flexibility auxiliary endoscope assembly for use with an endoscope also comprising a collar assembly 114, 116 operative to secure together at least said endoscope, said at least one flexible elongate element and said flexible sleeve (see Fig. 6 and Col. 4, Lines 50-63).

In regard to claims 14-17, 32, 36-38 and 51-54, Kotmel et al. disclose an enhanced flexibility auxiliary endoscope assembly for use with an endoscope wherein said inflatable balloon can be inflated to a diameter 3-10 times larger than its diameter when not inflated and wherein the inner diameter of said channel is in the range of 3 - 6 mm (see Col. 5, Lines 18-38).

In regard to claims 18-20, 33-35, 55-57, 65-66, 70-71, 74-75 and 82-83, Kotmel et al. disclose an enhanced flexibility auxiliary endoscope assembly for use with an endoscope also comprising inflation control subassembly operative to facilitate at least one of inflation and deflation of said inflatable balloon (see Col. 11, Lines 1-14).

Claims 7-8, 26, 28, 43, 47, 58 and 76 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL07/00600

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

6,585,639 to Kotmel et al. in view of U.S. Patent No. 6,309,346 to Farhadi.

In regard to claims 7-8, 26, 28, 43, 47, 58 and 76, Kotmel et al. disclose an enhanced flexibility auxiliary endoscope assembly for use with an endoscope, the assembly comprising: at least one flexible elongate element; and a flexible sleeve 26 having a first lumen 62 for accommodating a distal portion of an endoscope 14 capable of assuming at least a first curvature and a second lumen 64 for accommodating said at least one flexible elongate element, said second lumen being configured to allow said at least one flexible elongate element to assume said at least first curvature as well as at least a second curvature about said first curvature, thereby to enhance flexibility of said auxiliary endoscope assembly (see Figs. 1, 3d and Col. 4, Lines 30-50, Col. 9, Lines 32-38). Kotmel et al. are silent with respect to wherein said channel is defined at least in part by a coil spring and telescoping channel elements. Farhadi teach of an analogous apparatus having a coil spring used to eject an internal tube into the bowel lumen by force inside the external tube (see Figs. 7-8 and Col. 9, Lines 25-65). It would have been obvious to one skilled in the art at the time the invention was made to include a coil spring in the apparatus of Kotmel et al. to telescopically eject the instrument within the lumen, thus resulting in a procedure requiring less effort and time for the physician and less pain and discomfort to the patient as taught by Farhadi. Claims 1-87 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.